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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/266,889 03/12/99 SCHNEIDER

M 1201-71

EXAMINER

HM12/0514

NIXON & VANDERHYE P.C.
1100 N GLEBE ROAD
8TH FLOOR
ARLINGTON VA 22201

HARTLEY, M

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

05/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/266,889

Applicant(s)

SCHNEIDER ET AL.

Examiner

Michael G. Hartley

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 14, 16, 18, 19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14, 16, 18, 19 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 1619

Response to Amendment

The amendment filed 3/16/2001 has been entered. Claims 8, 10-13, 15, 17, 20-22 and 24-26 have been canceled. Claims 1-7, 9, 14, 16, 18, 19 and 23 have been amended.

Response to Arguments

Any previous rejections, which are not reiterated herein, have been obviated.

Applicant asserts that, since the claims were copied from the claims of U.S. patents 5,573,751 and 5,409,688 and the present application has an effective filing date earlier than the patent claims, an interference should be declared.

This is not found persuasive because, as set forth in the office action, the effective filing date of the instant application has not been determined to be the date of the earliest filed application, as stated by applicant. Also, the claims do not appear to be substantially copied from the patents. For example, it is noted that patent '751 has a reexamination certificate issued therein and the '688 claims are drawn to free gasbubbles, and do not recite stabilized microbubbles as instantly claimed. Since the claims of the instant application have not been found allowable for the reasons of record, an interference has not been declared.

Applicant argues that the determination of the effective filing date as set forth by the examiner in the office action mailed 9/18/2000 is incorrect.

Applicant asserts that the series of applications describes "Freons" describes the use of the specific gas species' claimed.

This is not found persuasive because the description of a broad genus (e.g., Freon) does not show support for specific species' encompassed therein, given the large number of gas species' encompassed thereby. There is no showing that applicant had possession of these specific gases which are broadly encompassed by the term Freon at the time of the claimed priority, let alone, has possession of these specific gas species with any surfactant given that the priority documents only described the use of certain materials as a stabilizer. The concept of using a surfactant for stabilizing the microbubbles in

Art Unit: 1619

combination with the specific gas species' as claimed was not conveyed in the priority documents, but the claimed combination of a surfactant with the specific gas species' as claimed was only described in the instant application, filed March 5, 1999, as set forth in the office action mailed 9/18/2000.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-7, 9, 14, 16, 18, 19 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Klaveness '856, Unger '429, Unger '112, Quay '094 and Quay '524, for the reasons set forth in the office action mailed 9/18/2000.

Claims 1-7, 9, 14, 16, 18, 19 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Lohrmann '597, for the reasons set forth in the office action mailed 9/18/2000.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9, 14, 16, 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaveness '856, Unger '429, Unger '112, Quay '094 and Quay '524, for the reasons set forth in the office action mailed 9/18/2000.

Art Unit: 1619

Claims 1-7, 9, 14, 16, 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohmann '597, for the reasons set forth in the office action mailed 9/18/2000.

Claims 1-7, 9, 14, 16, 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albayrak '954 and Rossling '697, for the reasons set forth in the office action mailed 9/18/2000.

Applicant's arguments filed 3/16/2001 have been fully considered but they are not persuasive. Applicant asserts that Klaveness '856, Unger '429, Unger '112, Quay '094 and Quay '524, Lohmann '597, Albayrak '954 and Rossling '697 are not prior art, since applicant is entitled to benefit of priority, to a date prior to the effective filing dates of these patents.

This is not found persuasive, since the actual effective priority date for the instant invention has been determined as March 5, 1999, as set forth in the office action mailed 9/18/2000 and reiterated herein.

Thus, the cited references do qualify as prior art for the instantly claimed invention.

Claims 1-7, 9, 14, 16, 18, 19 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rossling '863, Tickner '251, Tickner '885, Illum, Albayrak, Glajch '631, Swanson and Hillman in view of Lincoff, Lincoff, Gardner, Jacobs and the Dupont Technical Bulletin, for the reasons set forth in the office action mailed 9/18/2000.

Applicant's arguments filed 3/16/2000 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant asserts that Lincoff I, Lincoff II, Gardner and Jacobs teach away from the use of perfluorocarbons as ultrasound contrast agents since gas expansion in the blood stream could lead to serious health effects (e.g., an embolism).

Art Unit: 1619

This is not found persuasive because Rossling '863, Tickner '251, Tickner '885, Illum, Albayrak, Glajch '631, Swanson and Hillman teach contrast agents for ultrasound imaging which may comprise various gases, such as, halogenated hydrocarbons, Freons, etc., which when used in small amounts in microparticles would not lead to an embolism, while Lincoff I, Lincoff II, Gardner and Jacobs teach that fluorinated gases are safe for *in vivo* use. One of ordinary skill in the art would not expect that the amounts of gas used in the microparticles for ultrasound contrast agents would lead to embolism. However, one of ordinary skill in the art would have been motivated to employ the gases taught by Lincoff I, Lincoff II, Gardner and Jacobs as the insoluble gases used in the contrast agents disclosed by Rossling '863, Tickner '251, Tickner '885, Illum, Albayrak, Glajch '631, Swanson and Hillman because they are known to be safe for *in vivo* use. Additionally, the Dupont Technical Bulletin teaches that Freons, as disclosed by Tickner, include gases, which are the same as those instantly claimed.

Applicant asserts that while Dupont defines gases that are defined by Freons, there is no teaching that these gases may be used in an ultrasound contrast agent.

This is not found persuasive because Tickner teaches the use of Freons for ultrasound contrast agents, while the cited patents teach the use of similar halogenated gases for ultrasound contrast agents.

Double Patenting

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. patent Nos. 5,413,774, 5,578,292, 5,686,060, 5,556,610, 5,445,813, 5,518,991, 5,597,549, 5,567,414, 5,711,933, 5,380,519, 5,531,980, 5,271,928, 5,643,553 and 5,658,551, for the reasons set forth in the office action mailed 7/18/2000.

Applicant's request that this rejection be held in abeyance until the claims are otherwise indicated as being allowable is acknowledged.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending application serial nos. 08/740,653, 08/832,950, 08/637,346, 09/115,963, 08/848,912, 09/021,367, 08/855,055, 08/810,447, 08/910,149,

Art Unit: 1619

09/910,152, 08/947,196, 08/893,371, 09/002,710, 09/021,150, 09/225,293, 09/253,536, 09/263,105, 09/401,829, 08/401,835, 08/401,836, 09/401,837 and 09/401,838 for the reasons set forth in the office action mailed 7/18/2000.

Applicant's request that this rejection be held in abeyance until the claims are otherwise indicated as being allowable is acknowledged.

Conclusion

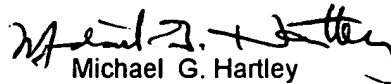
No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on 7:30-5 off alternative Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Michael G. Hartley
Primary Examiner
Art Unit 1619

MH
May 11, 2001